

REMARKS

The Office Action has been carefully reviewed. No claim is allowed. Claims 1-3 presently appear in this application and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Claims 1-4 and 6 have been rejected under 35 U.S.C. §101 because the examiner states that the claimed invention is not supported by either a specific and substantial credible utility or a well-established utility. The examiner states that it can be alleged that any protein which is expressed in a tissue-specific manner can be employed to detect the tissue in which it is expressed in a sample. The examiner then likens the asserted utility to be analogous to the assertion that a particular protein can be employed as a molecular weight marker, which is neither a specific or substantial utility. The examiner concludes that applicants' asserted utility is not substantial because any protein which is expressed in neuronal cells could be used for the same purpose with equal level of success. This rejection is respectfully traversed.

Applicants fully disagree with the examiner's characterization of the ARMS polypeptide which is localized

specifically to growth cones and the synaptic region of neurons and nowhere else. The claimed polypeptide is not a general tissue marker which is merely expressed in a tissue-specific manner in neurons but rather is one of only three known polypeptides, from among the large number of tissue-specific polypeptides expressed in neurons, which can be used to specifically visualize only a particular region of neurons, the growth cones, as supported in the present specification at page 27. As would be well recognized by those of skill in the art, growth cones of neurons are important to visualize for determining whether or not neurons are alive and making synapses. Accordingly, the situation here is not analogous to the example of molecular weight markers where any protein can serve as a molecular weight marker. It is certainly not true that any protein which is expressed in neuronal cells could be used for the same purpose with equal level of success.

Therefore, the asserted utility is not a throwaway utility or a non-specific utility that would apply to virtually every member of a general class of materials, i.e., all proteins expressed in neurons.

Attached hereto is a 1.132 declaration executed by Moses Chao, directed to the issue of a specific and substantial credible utility. Certainly the asserted utility

is credible. This prong of the three prong analysis for utility has not been questioned by the examiner. As companies have seen fit to commercialize antibodies to the only other known growth cone-specific polypeptides, VAMP-2 and GAP-43 (copies of two representative publications, Tojima et al., *Nature Neuroscience* 10(1):58-66, 2007, and Meiri et al., *PNAS* 83:3537-3541, 1986, directed to these two polypeptides, are attached hereto), there is indeed an interest and real world utility in the art to visualize the polypeptides specifically localized to the growth cones and synaptic regions of neurons. Accordingly, the presently claimed polypeptide does indeed meet the requirement of 35 U.S.C. §101 for a specific and substantial credible utility.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 1-4 and 6 have also been rejected under 35 U.S.C. §112, first paragraph, because the examiner takes the same position as in the above utility rejection that because the claimed invention is not supported by either a specific and substantial credible asserted utility or a well-established utility, one of skill in the art would not know how to use the claimed invention. This rejection is respectfully traversed.

For the same reasons as discussed above in the §101 utility rejection, the presently claimed polypeptide does indeed meet the requirement of a specific and substantial credible utility. Therefore, one of skill in the art would know how to use the presently claimed polypeptide for the asserted specific and substantial credible utility.

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

Claims 1, 4 and 6 have been rejected under 35 U.S.C. §112, first paragraph, for lack of adequate written description of fragments. This rejection is obviated by the amendment to the claims to delete "fragments" without prejudice.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claims 1-4 and 6 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection is obviated by the amendment to the claims.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting

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their allowance. Favorable consideration and early allowance
are earnestly urged.

Respectfully submitted,

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